" 510(k) SUMMARY "

MAR 2 8 2012

K112948

Submitter's Name: *Jiangsu Healthy Way Medical Equipment Co., Ltd.*
Qianjinhe Road, Xinfeng, Danfu District, Zhenjiang, Jiangsu, China, 212141

Date summary prepared: September 23, 2011

Device Name:

Proprietary Name:	Jiangsu Healthy Way Aluminum Mechanical Wheelchair
Common or Usual Name:	Mechanical Wheelchair
Classification Name:	Mechanical Wheelchair, Class I,
Regulation Number:	21 CFR 890.3850
Product Code:	IOR

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The Jiangsu Healthy Way Aluminum Mechanical Wheelchair is indoor / outdoor wheelchair that has a base with four-wheeled with a seat. The device can be disassembled for transport and it is foldable easily. The device uses a standard sling type back and seat, the upholstery fabric meets the resistant to ignition source smouldering cigarette, and match flame equivalent.

Literature for Performance Testing:

Jiangsu Healthy Way Aluminum Mechanical Wheelchair meets the applicable performance requirements as specified in ANSI/RESNA WC vol. 1 and ISO 7176 Wheelchair series standards including:

- EN 1021-1 /-2 Assessment of the ignition of upholstered furniture, 2006.
- ISO7176-1 Wheelchairs - Part 1: Determination of Static Stability, 1999.
- ISO7176-3 Wheelchairs - Part 3: Determination of effectiveness of brakes, 2003.
- ISO7176-5 Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space, 2008.
- ISO7176-7 Wheelchairs - Part 7: Measurement of seating and wheel dimensions, 1998.
- ISO7176-8 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths, 1998.
- ISO7176-11 Wheelchairs - Part 11: Test dummies, 1992.

- ISO7176-13 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces, 1989.
- ISO7176-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labelling, 1996.
- ISO7176-16 Wheelchairs - Part 16: Resistance to ignition of upholstered parts -- Requirements and test methods, 1997.
- ISO7176-22 Wheelchairs - Part 22:Set-up procedures, 2000.

Legally marketed device for substantial equivalence comparison:

KAIYANG Aluminum Wheelchair (K101998)

Summary for substantial equivalence comparison:

From the above comparison table the intended use between the subject device: Jiangsu Healthy Way Aluminum Mechanical Wheelchair and predicate device: KAIYANG Aluminum Wheelchair (K101998) are the same structure which are made by similar Aluminum. Mainframes of two devices are same foldable and same weight capacity. There are similar removable desk-length armrest and same swing-away detachable elevating footrest. Besides, back upholstery material is also the same resistance-ignitability fabric and also meets the California Technical standard for flame retardant. The overall appearance differences are not safety aspect. Thus the new device is substantially equivalent to the predicate device.

Dr. Jen, Ke-Min
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Jiangsu Healthy Way Medical Equipment Co., Ltd.
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Dr. Jen Ke-Min
No. 58 Fu Chiun Street
Hsin Chu City
Taiwan, ROC 30067

MAR 2 8 2012

Re: K112948
Trade/Device Name: Aluminum Mechanical Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: March 14, 2012
Received: March 21, 2012

Dear Dr. Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): K112948

Device Name: *Aluminum Mechanical Wheelchair*

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112948